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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,524	12/29/2003	Richard E. Parizek	I 1995.184 US D1	8568

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PATENT DEPARTMENT
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
05/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/748,524	PARIZEK ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 April 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *18 April 2008*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *46-48*.
   Claim(s) withdrawn from consideration: *None*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Mark Navarro/
Primary Examiner, Art Unit 1645

The rejection of claims 46-48 under 35 U.S.C. 103(a) as being unpatentable over Roberts (WO 94/22476, published October 13, 1994) in view of Lund (3,920,811 published November 18, 1975) is maintained because it would have been prima facie obvious at the time of applicants' invention to apply the encapsulating polymer adjuvant of Lund's to Roberts method of immunizing cattle in order to avoid irritation and significant lesion formation at the injection site.

Applicants argue that Roberts teaches against using an encapsulation polymer adjuvants that releases antigens slowly at the site of injection. However, Roberts is relied upon because it reasonably suggest to one having ordinary skill the art multicomponent vaccines comprising encapsulating adjuvants administered in a low dose volume of about 2 ml. Therefore, no more than routine skill would have been required to exchange the adjuvant of Roberts for the commercially available and functionally equivalent encapsulating polymer adjuvant of Lund since Lund teaches that adjuvant polymers are retained at the injection site for prolonged slow release of antigens.

Roberts disclosed the polymer adjuvant and refers to polymer adjuvants as nonpreferred embodiments. Polymer adjuvants, including carbopol, which are known to readily absorb water and due to its hydrophilic nature, and cross-linked structure, are known to useable for controlled release drug delivery systems. Roberts even cites prior art references teaching the adjuvants can be admixed in liposomes. Lund teaches an adjuvant polymers, such as CARBOPOL, are retained at the site for prolonged slow release that acts by adsorbing the active agent onto the polymer. Roberts and Lund teach the instant claims, because it is likely that a 2ml of the vaccine will result in a smaller lesion as compared with a 5ml injection of that same vaccine. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success by exchanging the readily dispersible soluble adjuvants of Roberts for the adjuvant polymer of Lund because Roberts teaches that clostridial vaccines require adjuvants in order to increase potency and enhance stability of the bacterins and that clostridial vaccines are known to include CARBOPOL polymers. Thus the rejection is maintained.

The rejection of claims 46-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record. The rejection is on the grounds that neither the specification nor originally presented claims provides support for a method of immunizing cattle without significant injection site lesion formation comprising amount of injecting into said cattle about 2ml of a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from six or seven clostridial organisms, a protective antigen component from at least one non-clostridial organism which is Moraxella bovis (M.bovis) and an encapsulating polymer adjuvant whereby the encapsulating polymer adjuvant releases antigens slowly at the site of injection and whereby injection site lesion formation is reduced at least 41% compared with an injection of 5 ml of said vaccine into said cattle and effective immunization is accomplished. Theefore the rejection is maintained.